

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

DMB

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Transmissible Spongiform Encephalopathies Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed to the public.

Name of Committee: Transmissible Spongiform Encephalopathies Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on October 25, 2001, from 8 a.m. to 3:30 p.m., and on October 26, 2001, from 8 a.m. to 4:30 p.m.

Location: Holiday Inn, Kennedy Ballroom, 8777 Georgia Ave., Silver Spring, MD.

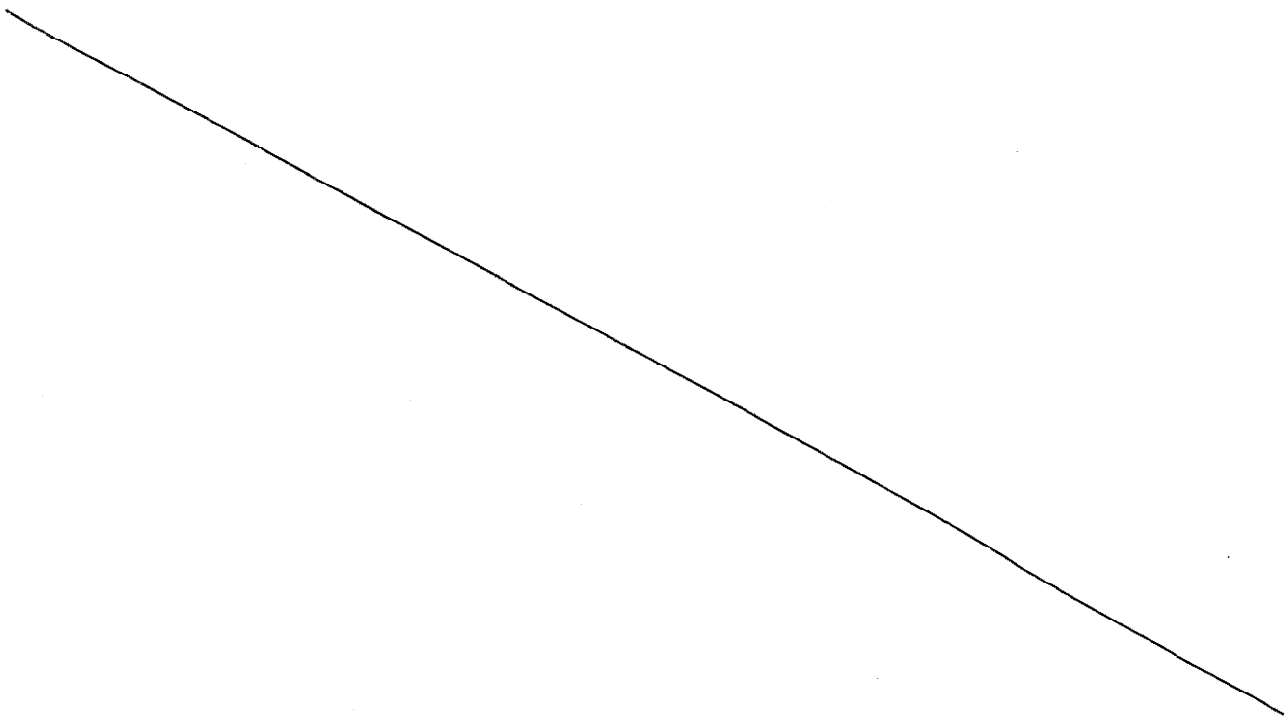
Contact: William Freas, or Sheila D. Langford, Center for Biologics Evaluation and Research (HFM-71), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-0314, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12392. Please call the Information Line for up-to-date information on this meeting.

Agenda: On October 25, 2001, the committee will discuss FDA's draft document entitled "Guidance for Industry: Revised Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and Variant Creutzfeldt-Jakob Disease (vCJD) by Blood and Blood Products" (published in the **Federal Register** on August 29, 2001 (66 FR 45683), <http://www.fda.gov/cber/gdlns/cjdvcjd.pdf>). Later that morning the committee will discuss amino acid sourcing and production, and the theoretical risk of transmission of the BSE agent through their

use in vaccines, other biologicals and human drugs. On October 26, 2001, the committee will discuss the risk of bovine brains and other neurological tissue for human use.

Procedure: On October 25, 2001, from 8 a.m. to 1:10 p.m. and from 1:40 p.m. to 3:30 p.m., and on October 26, 2001, from 8 a.m. to 4:30 p.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by October 18, 2001. Oral presentations from the public will be scheduled between approximately 9 a.m. to 9:30 a.m., and 1:40 p.m. to 2:10 p.m. on October 25, 2001; and between 1 p.m. to 1:30 p.m. on October 26, 2001. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before October 18, 2001, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

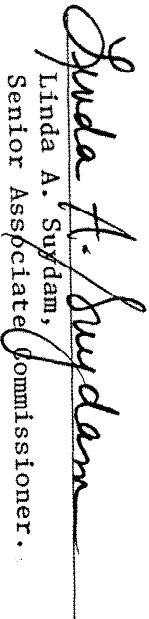
Closed Committee Deliberations: On October 25, 2001, from 1:10 p.m. to 1:40 p.m., the meeting will be closed to permit discussion and review of trade secret and/or confidential information (5 U.S.C. 552b(c)(4)).



Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app.

2).

Dated. October 4, 2001.


Linda A. Suydam,
Senior Associate Commissioner.

[FR Doc. 01-?? ??? Filed ??-??-01; 8:45 am]

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